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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Declaration Regarding Emergency Use of Treatment for Uncontrolled Hemorrhage Due to Agents of Military Combat

AGENCY: Department of Health and Human Services, Office of the Secretary

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to the Federal Food, Drug, and Cosmetic (FD&C) Act. On June 7, 2018, Patrick M. Shanahan, Deputy Secretary of Defense, determined in accordance with the Federal Food, Drug and Cosmetic Act, as delegated by the Secretary of Defense, that there is a military emergency or significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces. More specifically, U.S. Forces are now deployed in multiple locations where they serve at heightened risk of an enemy attack with agents of military combat, including firearms, projectiles, and explosive devices, that may cause major and imminently life-threatening combat casualties involving uncontrolled hemorrhage. On the basis of this determination, on July 9, 2018 the Secretary declared that circumstances exist justifying the authorization of emergency use of Freeze Dried Plasma (FDP) to treat uncontrolled hemorrhage due to agents of military combat (e.g., firearms, projectiles, and explosive devices) in emergency situations when plasma is not available for use or its us is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The declaration is effective July 9, 2018

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing 1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or 2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: 1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear ("CBRN") agent or agents; 2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act[1] sufficient to affect national security or the health and security of United States citizens living abroad; 3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack

[1] 42 U.S.C. § 247d-6b, which states: "[t]he Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis-- (i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and (ii) determine which of such agents present a material threat against the United States population sufficient to affect national security."

with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or 4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met. The determination of a military emergency or significant potential for a military emergency by the Deputy Secretary of Defense, and the declaration that circumstances exist justifying emergency use of French FDP by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for FDP in emergency situations when plasma is not available for use or its use is not practical for emergency use under section 564 of the FD&C Act.

II. Determination of a Military Emergency or Significant Potential for a Military Emergency by the Deputy Secretary of Defense

On June 7, 2018, Patrick M. Shanahan, Deputy Secretary of Defense, determined in accordance with section 564(b)(1)(B) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1)(B), as delegated by the Secretary of Defense, that there is a military emergency or significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces. The Deputy Secretary further stated

that, more specifically, U.S. Forces are now deployed in multiple locations where they serve at heightened risk of an enemy attack with agents of military combat, including firearms, projectiles, and explosive devices, that may cause major and imminently life-threatening combat casualties involving uncontrolled hemorrhage.

III. Declaration of the Secretary of Health and Human Services

On July 9,2018, on the basis of the Deputy Secretary of Defense's determination that there is a military emergency or significant potential for a military emergency involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces, I declared that circumstances exist justifying the authorization of emergency use of FDP to treat uncontrolled hemorrhage due to agents of military combat (e.g., firearms, projectiles, and explosive devices) in emergency situations when plasma is not available for use or its use is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of any EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the Federal Register as required under section 564 of the FD&C Act.

Alex M. Azar II
Secretary
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